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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,823	08/16/2006	Graziana Taramino	BB1545 US PCT	8958
23906 7590 04/29/2011 E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1122B 4417 LANCASTER PIKE WILMINGTON, DE 19805				
EXAMINER BAUM, STUART F				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
04/29/2011		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

### Office Action Summary

**Application No.**

10/586,823

**Applicant(s)**

TARAMINO ET AL.

**Examiner**

STUART BAUM

**Art Unit**

1638

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 13 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/20/2007
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: sequence search results

### **DETAILED ACTION**

1. Claims 1-11, 13 and 15-19 are pending.
2. Applicant's election without traverse of Group I, including SEQ ID NO:5, 6, 9 and 10 in the reply filed on 3/8/2011 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 12, 14 and 20-22 have been canceled.

3. Claims 1-11, 13 and 15-19 including SEQ ID NO:5, 6, 9 and 10 are examined in the present office action.

### **Information Disclosure Statement**

4. The information disclosure statement filed 9/20/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication. In the instant application, the lined thru citation does not include a date. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### **Claim Objection**

5. Claims 1-6, and 8-9 are objected to for reciting "one of SEQ ID NO:6" instead of --SEQ ID NO:6--. Correction is requested.

Claim 10 is objected to for misspelling "sub-sequence".

Claims 11 and 13 are objected to for misspelling "sub-fragment".

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, line 13, "a nucleic" should be amended to --the nucleic-- for proper antecedence.

### **Written Description**

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7, 10-11, 13 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide required for proper root formation, wherein the polypeptide has an amino acid sequence of at least 70%, 75%, 80%, 85%, 90%, 95% and 99% identity to SEQ ID NO:6, or a functionally equivalent sub-fragment thereof wherein said sub-fragment is useful in antisense inhibition or co-suppression of said nucleotide sequence, or recombinant DNA construct comprising said sub-fragment; or plant, seed or method comprising said construct.

Applicants disclose the rootless for crown and seminal roots (RTCS) gene sequence is set forth in SEQ ID NO:1 and SEQ ID NO:5 is the ORF of SEQ ID NO:1 minus an intron, i.e., nucleotides 2779-3059 and 3160-3610 of SEQ ID NO:1 (page 22 and page 4). SEQ ID NO:6 is the encoded protein. Applicants disclose Figure 1 shows an alignment of the maize RTCS from inbred Mo17 (SEQ ID NO:6), a deduced RTCS homolog from rice (SEQ ID NO:8), maize RTCS from inbred B73 (SEQ ID NO:30) and the boxed residues are conserved motifs unique to RTCS proteins (page 37, lines 29-33).

The Applicants do not identify essential regions of the protein encoded by SEQ ID NO:5, nor do Applicants describe any polynucleotide sequences that encode a polypeptide having at least 70% identity to SEQ ID NO:6 that is required for proper root formation nor do Applicants disclose sub-fragments used in antisense or co-suppression gene inhibition.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a protein falling within the scope of the claimed genus of polynucleotides which encode a polypeptide having at least 70% identity with SEQ ID NO:6 wherein the polypeptide is required for proper root formation. Applicants only disclose two maize RTCS polynucleotide sequences and one rice RTCS sequence of SEQ ID NO:6, 30 and 7, respectively and present an alignment with conserved domains highlighted. Applicants do not indicate the percent identities between the sequences nor do they disclose if all of the sequences are required for proper root formation. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by Eli Lilly. Furthermore, given the lack of description of the necessary elements essential

for the RTCS protein of SEQ ID NO:6, it remains unclear what features identify a maize RTCS protein. Both the prior art and the specification fail to disclose a correlation between the structure of the claimed sequences and the recited function. Since the genus of said proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

### **Enablement**

8. Claims 1-11, 13 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide required for proper root formation, wherein the polypeptide has an amino acid sequence of at least 70%, 75%, 80%, 85%, 90% , 95% or 99% identity to SEQ ID NO:6, or

wherein the amino acid sequence comprises SEQ ID NO:6, or wherein the nucleotide sequence comprises SEQ ID NO:5, or a functionally equivalent sub-fragment thereof wherein said sub-fragment is useful in antisense inhibition or co-suppression of said nucleotide sequence, or recombinant DNA construct comprising said sub-fragment; or plant, seed or method of altering root structure during plant development comprising said construct.

Applicants disclose homozygous *rtcs/rtcs* plants were scored as completely lodged plants when grown in the field for 40 days or more (page 21, top paragraph). Applicants disclose the rootless for crown and seminal roots (RTCS) gene sequence is set forth in SEQ ID NO:1 and SEQ ID NO:5 is the ORF of SEQ ID NO:1 minus an intron, i.e., nucleotides 2779-3059 and 3160-3610 of SEQ ID NO:1 (page 22 and page 4). SEQ ID NO:6 is the encoded protein. Applicants disclose Figure 1 shows an alignment of the maize RTCS from inbred Mo17 (SEQ ID NO:6, a deduced RTCS homolog from rice (SEQ ID NO:8), maize RTCS from inbred B73 (SEQ ID NO:30) and the boxed residues are conserved motifs unique to RTCS proteins (page 37, lines 29-33). Applicants disclose SEQ ID NO:6 comprises a LOB domain (page 37, Example 13).

Applicants have not reduced to practice their invention. Applicants have not transformed a plant with any of the claimed polynucleotide sequences and produced a plant with altered root structure or any agronomically useful phenotype. Applicants only disclose that *rtcs/rtcs* mutant plants were completely lodged after 40 days in the field (see above). The state-of-the-art teaching transforming plants with nucleic acids encoding polypeptides comprising a LOB domain produces unexpected results. Ma et al (2007, Plant Science 172(2):181-188) teach ectopic expression of TaAS2 in Arabidopsis, wherein TaAS2 is a LOB containing protein, mainly



resulted in the adaxialization of abaxial mesophyll tissues and the alteration of the vascular pattern in leaves and petioles (abstract).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode a protein exhibiting 70% identity to SEQ ID NO:6 will encode a protein with the same activity as a protein encoded by SEQ ID NO:5. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2<sup>nd</sup> paragraph).

Applicants have not provided any teachings for one skilled in the art to predict and isolate nucleic acid sequences that encode a protein with the necessary activity to be operable in Applicants' invention. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:5 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids

can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

The Office contends the recited functional limitation “encoding a polypeptide required for proper root formation” is not specific and is not assayable. Applicants have not taught by way of disclosure or example an assay that one of ordinary skill in the art can use to test the multitude of sequences that are encompassed by Applicants’ broad claims. Without an assay, one of ordinary skill would have no way of discerning which of the sequences would not be operable in Applicants’ invention.

In regards to functionally equivalent sub-fragment, state-of-the-art teach sense and antisense constructs can behave unpredictably when transformed into a heterologous plant species. Colliver et al (1997, Plant Mol. Biol. 35:509-522) showed that transformation of bird’s foot trefoil with a construct that was antisense to bean chalcone synthase unexpectedly resulted in transformants with increased levels of chalcone synthase transcripts (page 519, left column, 2<sup>nd</sup> paragraph). Montgomery et al (Trends in Genetics, July 1998, 14(7):255-258) teach that not all transgenes can cause co-suppression in plants and that there is no basis for predicting which transgenes would have this effect (page 257, column 1, last paragraph).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:5 as probes or by designing primers to undisclosed regions of SEQ ID NO:6 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed alter root structure during plant development.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

If the claims are enabled, then the following rejections are set forth.

### **Claim Rejections - 35 USC § 102**

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-11, 13 and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al (1999, Pub. No.: US 2004/0034888 A1).

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide required for proper root formation, wherein the polypeptide has an amino acid sequence of at least 70%, 75%, 80%, 85%, 90% , 95% or 99% identity to SEQ ID NO:6, or wherein the amino acid sequence comprises SEQ ID NO:6, or wherein the nucleotide sequence comprises SEQ ID NO:5, or a functionally equivalent sub-fragment thereof wherein said sub-fragment is useful in antisense inhibition or co-suppression of said nucleotide sequence, or recombinant DNA construct comprising said sub-fragment; or plant or seed comprising said construct.

Liu et al disclose a nucleic acid sequence of SEQ ID NO:2146 exhibiting 100% identity to Applicants' SEQ ID NO:5 and encoding a polypeptide exhibiting 100% identity to Applicants' SEQ ID NO:6 (search results included). Liu et al disclose said sequence in a

recombinant DNA construct and a plant and seed comprising said construct or wherein the plant is rice (page 6, paragraph 66; pages 7-8, paragraphs 67-82). The Office contends the sequence of Liu et al also comprises a functionally equivalent sub-fragment of Applicants' sequence and as such, Liu et al anticipate the claimed invention.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11, 13, 15-16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shuai et al (2002, Plant Physiology 129(2):747-761).

The claims are drawn to a functionally equivalent sub-fragment of the isolated polynucleotide of claim 1, wherein said sub-fragment is useful in antisense inhibition or co-suppression of expression the nucleic acid sequence of claim 1, or a recombinant DNA construct comprising said sub-fragment operably linked to a promoter; plant or plant cell or seed comprising said construct.

Shuai et al disclose a nucleic acid sequence encoding a protein exhibiting 40% identity to Applicants' SEQ ID NO:6 (search result included). Shuai et al disclose the encoded protein comprises a LOB domain. Applicants disclose SEQ ID NO:6 comprises a LOB domain (page 37, Example 13). Shuai et al disclose a construct comprising said nucleic acid sequence and a plant transformed therewith (page 751, left column, bottom paragraph). The Office contends the teachings of Shuai et al inherently produce seeds because Shuai et al use the floral dip transformation procedure (page 758, right column, middle paragraph), and as such, Shuai et al anticipate the claimed invention.

**Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 16 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claim to recite that the seed comprise the construct that was introduced into the parent would overcome the rejection.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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